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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,995	11/21/2003	Marcel Tijsterman	2183-6201US	3648
24247	7590	07/12/2006	EXAMINER	
TRASK BRITT P.O. BOX 2550 SALT LAKE CITY, UT 84110			LU, FRANK WEI MIN	
			ART UNIT	PAPER NUMBER
			1634	
DATE MAILED: 07/12/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/719,995

Applicant(s)

TIJSTERMAN ET AL.

Examiner

Frank W. Lu

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-14, drawn to a method for determining whether a gene product involved in preventing a replication error in a cell, classified in class 435, subclass 6.
  - II. Claims 15, 16, 22-25, and 29, drawn to an isolated and/or recombinant gene (claims 15 and 16), a kit (claims 22-25), and a gene delivery vehicle (claim 29), classified in class 536, subclass 23.1 and class 435, subclass 320.1.
  - III. Claims 17-21, drawn to a method for determining whether a cell is predisposed to display a nucleic acid repeat instability phenotype.
  - IV. Claims 26-28 and 35-38, drawn to a method for determining whether a compound is capable of influencing a process involved in preventing a replication error in a cell.
  - V. Claim 30, drawn to a method for influencing a process involved in preventing a replication error in a cell comprising providing the cell with a gene delivery vehicle.
  - VI. Claim 31, drawn to a method of treating a subject.
  - VII. Claims 32-34, drawn to a non-human animal.
  - VIII. Claim 39, drawn to a method for typing a cell.
2. The inventions are distinct, each from the other because of the following reasons:

Groups I, III to VI and VIII and Group II are distinct and independent inventions in that they are directed to a method and a product which have different designs, modes of operation, and effects.

Group I and Groups III to VI and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group I such as determining whether a gene product involved in preventing a replication error in a cell in claim 1 is not required for Groups III to VI and VIII while the search required for Group III such as determining whether a cell is predisposed to display a nucleic acid repeat instability phenotype in claim 17 or the search required for Group IV such as determining whether a compound is capable of influencing a process involved in preventing a replication error in claim 26 or the search required for Group V such as a gene delivery vehicle in claim 30 or the search required for Group VI such as treating a subject in claim 31 or the search required for Group VIII such as typing a cell in claim 39 is not required for Group I.

Groups I, III to VI and VIII and Group VII are distinct and independent inventions in that they are directed to a method and a product which have different designs, modes of operation, and effects.

Groups II and VI are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group II such as a gene delivery vehicle in claim 29 is not required for Group VI while the search required for Group VI such as a non-human animal in claim 32 is not required for Group II.

Group III and Groups IV to VI and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group III such as determining whether a cell is predisposed to display a nucleic acid repeat instability phenotype in claim 17 is not required for Groups IV to VI and VIII while the search required for Group IV such as determining whether a compound is capable of influencing a process involved in preventing a replication error in claim 26 or the search required for Group V such as a gene delivery vehicle in claim 30 or the search required for Group VI such as treating a subject in claim 31 or the search required for Group VIII such as typing a cell in claim 39 is not required for Group III.

Group IV and Groups V, VI and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group IV such as determining whether a compound is capable of influencing a process involved in preventing a replication error in claim 26 is not required for Groups V, VI and VIII while the search required for Group V such as a gene delivery vehicle in claim 30 or the search required for Group VI such as treating a subject in claim 31 or the search required for Group VIII such as typing a cell in claim 39 is not required for Group IV.

Group V and Groups VI and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group V such as a gene delivery vehicle in claim 30 is not required for Groups VI and VIII while the search required for

Group VI such as treating a subject in claim 31 or the search required for Group VIII such as typing a cell in claim 39 is not required for Group V.

Groups VI and VIII are distinct and independent inventions in that they are directed to methods which comprise different method steps. As a result, different and distinct searches will have to be performed. For example, the search required for Group VI such as treating a subject in claim 31 is not required for Group VIII while the search required for Group VIII such as typing a cell in claim 39 is not required for Group VI.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

3. Specific Gene or Gene Composition Election Requirement Applicable to Groups II, IV and VIII

Each gene in Groups II, IV, and VIII reads on patentably distinct gene. Each gene in Groups II, IV, and VIII is patentably distinct because these genes are structurally unrelated and a further restriction is applied to each Group. Therefore, applicant must further elect a single gene or a composition comprising more than one gene. Applicant is advised that examination will be restricted to only elected single gene or elected composition and should not to be construed as a species election.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Priority***

4. Acknowledgment is made of applicant's claim for foreign priority based on an application (01201936.0) filed in Europe on May 22, 2001. It is noted, however, that applicant has not filed a certified copy of this application as required by 35 U.S.C. 119(b).

5. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

July 10, 2006



**FRANK LU**  
**PRIMARY EXAMINER**